K062871

Appendix A6 The 510(k) Summary

NOV 14 2006

Applicant & Submitter :	Lynton Lasers Limited
Address :	Lynton House, Manor Lane, Holmes Chapel, Cheshire, CW4 8AF, UK
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Contact Person :	Dr. Andrew J Berry AJBerry@lynton.co.uk
Preparation Date :	3rd July 2006
Device Submitted :	LumaCare LC-122M Non-coherent Light Source
Common Name :	Light Therapy Device
Classification Name :	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Product Code :	GEX
Predicate Device :	BLU-U Blue Light Photodynamic Therapy Illuminator Model 4170, manufactured by DUSA Pharmaceuticals, Inc. (K031805)
Device Description :	The LumaCare LC-122M Non-coherent Light Source is a high intensity lamp intended for the therapy of dermatological disorders such as moderate inflammatory acne vulgaris by emitting visible light in the wavelength range 400-440nm (blue) with fluences of order 10-100mW/cm^2. The principle parts of the system comprise of a desktop base unit and a Fibre Optic Probe (FOP) delivery system. The base unit contains a mains supplied power supply unit which powers a 250W halogen bulb, the duration of the illumination being controlled by a timing pcb with user-accessible controls. The FOP delivery system comprises of a ruggedised fibre bundle assembly and (crucially) an optical filter which selectively transmits only the therapeutic blue light. A mechanical fixture

	is also optionally available for holding the output of the FOP delivery system at an adjustable distance and direction relative to the skin treatment area.
Intended Use :	The LumaCare LC-122M Non-coherent Light Source is intended to provide therapeutic light to the body
Indications for Use :	The LumaCare LC-122M Non-coherent Light Source is generally indicated to treat dermatological conditions. The LumaCare LC-122M Non-coherent Light Source is specifically indicated to treat moderate inflammatory acne vulgaris.
Performance Data :	The pre-clinical testing includes Electrical Safety and EMC testing including the requirements of IEC 60601-1:1988/A1/A2 "Medical electrical equipment - General requirements for safety" and "IEC 60601-1-2:2002 "Medical electrical equipment - General requirements for safety. Collateral standard - Electromagnetic compatibility. Requirements and tests"
Substantial Equivalence :	The LumaCare LC-122M Non-coherent Light Source is substantially equivalent to the previously cleared BLU-U Blue Light Photodynamic Therapy Illuminator Model 4170. The LumaCare LC-122M has the same intended use and the same general and specific indications for use as the BLU-U. The spectral output, mode of operation and general operating principles for the LumaCare LC-122M are similar to or the same as the BLU-U. The LumaCare LC-122M and the BLU-U are both light device that are used to treat dermatological conditions by exposing the surface of the skin to light at precise wavelengths. Although there are some differences in method by which each device produces light and is delivered to the treatment area, these differences do not raise new questions of safety of efficacy. Thus, the LumaCare LC-122M Non-coherent Light Source is substantially equivalent to the BLU-U.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Lynton Lasers Limited
% Dr. Andrew J. Berry
Technical Director
Lynton House, Manor Lane
Holmes Chapel, Chesire CW 4 8 AF
United Kingdom

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Re: K062871
Trade/Device Name: LumaCare LC-122M Non-coherent Light Source
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: September 21, 2006
Received: September 25, 2006

Dear Dr. Berry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062871

Device Name: LumaCare LC-122M Non-coherent Light Source

Indications for Use: The LumaCare LC-122M Non-coherent Light Source is intended to provide therapeutic light to the body

The LumaCare LC-122M Non-coherent Light Source is generally indicated to treat dermatological conditions. The LumaCare LC-122M Non-coherent Light Source is specifically indicated to treat moderate inflammatory acne vulgaris.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062871